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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,661	10/17/2005	Kenneth Kao	50680-6 /slr	4668
7380 7590 04/19/2007 SMART & BIGGAR P.O. BOX 2999, STATION D 900-55 METCALFE STREET OTTAWA, ON K1P5Y6 CANADA			EXAMINER GUSSOW, ANNE	
			ART UNIT 1643	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/19/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/553,661

Applicant(s)

KAO ET AL.

Examiner

Anne M. Gussow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8-10 and 57-68 is/are pending in the application.
- 4a) Of the above claim(s) 9, 60 and 63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 10, 57-59, 61, 62 and 64-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/10/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: Sequence alignment.

DETAILED ACTION

1. Applicant's election with traverse of Group II, claims 1-4, 6, 7, 9, and 10, in the reply filed on February 27, 2007 is acknowledged. The traversal is on the ground(s) that the special technical feature is "the use of Pygopus gene in cancer and diagnostic therapy, not the Pygopus gene per se" and the date of the art cited in the restriction requirement (see page 8 of response): This is not found persuasive because while the use of the Pygopus gene may be novel, the method requires the Pygopus gene as a technical feature of the method and the Pygopus gene is not novel and is therefore not a special technical feature.

In regards to applicant's argument that Thompson, et al. (Nature Cell Biology Vol 4, published online April 22, 2002, as cited in prior action) is not prior art, the filing date of the provisional priority document for this application is April 17, 2003, thus Thompson, et al. is available as 102(a) prior art. Additionally, the PCT Search and Examination Guidelines state "there are no restrictions as to the age of the prior art document (whether it is 100 years old or was published one day prior to the "relevant date") so long as the document was made available to the public before the "relevant date"." (Page 104)

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 9, 60, and 63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable

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generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 27, 2007.

3. The restriction requirement contained a typographical error in the placement of claim 8 in Group I and claim 9 in Group II. Claim 8 is drawn to method of determining the presence of a protein, while claim 9 is drawn to a method of determining the presence of an mRNA. Applicant's response specifically elects "Group II (claims 1-4, 6, 7, 9, and 10), drawn to methods of determining the presence or absence of a cancer in a patient comprising determining the level of Pygopus protein" (see page 1 of the response, underline added). Therefore, claim 8 will be examined and claim 9 is withdrawn.

4. Claims 5-7 and 11-56 have been cancelled.

Claims 57-68 have been added.

Claims 1-4, 8, 10, 57-59, 61, 62, and 64-68 are under examination.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on February 10, 2006 has been fully considered and an initialed copy of the IDS is included with this Office Action.

Drawings

6. The description of Figure 6 on page 15 of the specification describes a color version of the Figure, however, no color drawing was received with the application.

Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Specification

7. The disclosure is objected to because of the following informalities: In the description of the figures on page 17 there are two descriptions of figure 9d, one of these is the description of figure 9e and on page 19 the description of figure 14 does not describe parts A and B of the figure. Additionally, if a color version of figure 6 is not being submitted, the description of the color figure on page 15 should be changed to represent the black and white figure.

Appropriate correction is required.

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8. The use of the trademarks Oligofectamine™, RNeasy™, Vectashield™, Effectene™ Transfection Kit, Nucleospin™, Hybond-ECL™, and siRNA/siAB™, have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Trademark symbols have not been included for the trademarks in this application. Appropriate correction is required.

Claim Objections

9. Claims 10 objected to because of the following informalities: the claim contains limitations of a non-elected invention in reciting the limitation of detecting hPygpo2 protein or mRNA. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 59 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 59 and 61 are indefinite for reciting "an antibody specifically reactive to hPygo2 protein". It is not clear what the reaction is, antibodies typically bind to antigens unless they are catalytic antibodies.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1-4, 8, 10, 57-59, 61, 62, and 64-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting hPygo2 protein in ovarian, breast, cervical and lung cancer, does not reasonably provide enablement for detecting hPygo2 protein in just any cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for determining the presence of a cancer in a patient by determining the level of expression of hPygo2 as shown in SEQ ID No.1 in a biological sample and comparing the level of hPygo2 to the level of expression in a normal biological sample. The claims are also drawn to a kit comprising the reagent capable of detecting hPygo2 protein in a biological sample.

Initially reported biomarkers show great promise, but subsequent studies often yield inconsistent conclusions or contradict the promising results (McShane, et al. European Journal of Cancer, 2005. Vol. 41, pages 1690-1696). Prognostic markers may be considered in the clinical management of a patient, while predictive markers are

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generally used to make specific choices between treatment options. (McShane, et al. page 1691). For example, prognostic markers may be used in determining whether a patient should receive adjuvant chemotherapy or how aggressive that therapy should be. Specifically, Andrews 2007 et al. (International Journal of Oncology, 2007. Vol. 30 No. 2, pages 357-63) teach hPygo2 protein levels to be elevated in ovarian, cervical, and neuroblastoma cell lines, but lower than in malignant breast cells Bt-474 and MCF-7 (page 358). Thus, a specific marker maintains different expression levels in different cell types and cancer types.

There is insufficient evidence or nexus that would lead the skilled artisan to predict the ability to detect hPygo2 protein in just any cancer cell. The specification does not teach detection of hPygo2 in a representative number of species of cancer.

In view of the lack of the predictability of the art to which the invention pertains the lack of established clinical protocols for detecting hPygo2, undue experimentation would be required to practice the claimed methods with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed methods and absent working examples providing evidence which is reasonably predictive that the claimed methods are effective for detecting hPygo2 in cancer cells, commensurate in scope with the claimed invention.

Conclusion

14. No claims are allowed.

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15. Claims 1-4, 8, 10, 57-59, 61, 62, and 64-68 are free of the prior art. The closest prior art is Kramps, et al. (WO/2002/077023A2, published October 3, 2002).

Kramps, et al. teach identification of a new component of the wingless signaling pathway, daughter of legless (DOLL). DOLL is identical to hPygo2 of the instant application (see sequence alignment). Kramps, et al. do not teach nor reasonably suggest a method for determining the presence or absence of a cancer in a patient by detecting DOLL protein.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow, Ph.D.

April 9, 2007

A handwritten signature in black ink, appearing to read 'L. Helms', is positioned above the printed name.

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER